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(54) **SYSTEM AND METHOD FOR MANAGING SURGICAL ARTICLES DURING A SURGICAL PROCEDURE**

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CPC ..... **G16H 40/20** (2018.01); **G06K 7/10217** (2013.01); **A61B 2050/375** (2016.02); **A61B 2090/0804** (2016.02); **A61B 90/98** (2016.02)

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See application file for complete search history.

(56)

**References Cited**

**U.S. PATENT DOCUMENTS**

3,941,132 A 3/1976 Lenaghan  
3,965,907 A 6/1976 Hardy et al.

(Continued)

**FOREIGN PATENT DOCUMENTS**

EP 0948940 A1 10/1999  
WO 9422580 A1 10/1994

(Continued)

**OTHER PUBLICATIONS**

Association of Operating Room Nurses, "Recommended Practices for Sponge, Sharps, and Instrument Counts", AORN Journal, vol. 83, No. 2, Feb. 2006, pp. 418-433.

(Continued)

*Primary Examiner* — Daryl C Pope

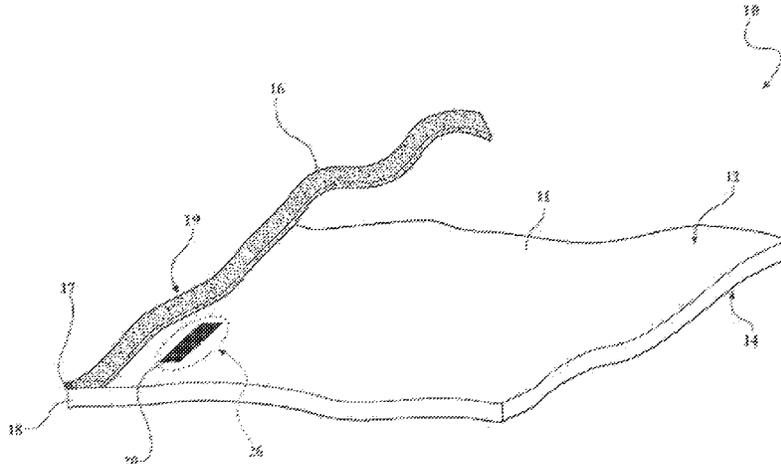
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**ABSTRACT**

System and method of managing one or more surgical articles, wherein the surgical article can include a surgical sponge comprising an identification element, and wherein managing can include counting, locating, or both. The identification element can be a RFID tag. The RFID tag stores unique identification information relative to the surgical sponge. The system and method for detecting RFID tags may include varying the power level of the RFID

(Continued)



interrogator to improve the accuracy of scanning the RFID tag or tags. A plurality of the RFID-tagged surgical articles (i.e., surgical sponges) may be packaged or bundled via a strap or within a container.

**18 Claims, 6 Drawing Sheets**

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*G06K 7/10* (2006.01)

(56) **References Cited**

U.S. PATENT DOCUMENTS

4,098,728 A 7/1978 Rosenblatt  
 4,114,601 A 9/1978 Abels  
 4,244,369 A 1/1981 McAvinn et al.  
 4,264,575 A 4/1981 Zimmerman et al.  
 4,477,256 A 10/1984 Hirsch  
 4,626,251 A 12/1986 Shen  
 4,639,253 A 1/1987 Dyer et al.  
 4,645,499 A 2/1987 Rupinskas  
 4,658,818 A 4/1987 Miller, Jr. et al.  
 4,711,996 A 12/1987 Drexler  
 4,718,897 A 1/1988 Elves  
 4,832,198 A 5/1989 Alikhan  
 4,917,694 A 4/1990 Jessup  
 5,031,642 A 7/1991 Nosek  
 5,041,103 A 8/1991 Rupinskas  
 5,045,080 A 9/1991 Dyer et al.  
 5,049,219 A 9/1991 Johns et al.  
 5,057,095 A 10/1991 Fabian  
 5,074,840 A 12/1991 Yoon  
 5,112,325 A 5/1992 Zachry  
 5,231,273 A 7/1993 Caswell et al.  
 5,374,813 A 12/1994 Shipp  
 5,443,082 A 8/1995 Mewburn  
 5,456,718 A 10/1995 Szymaitis  
 5,610,811 A 3/1997 Honda  
 5,629,498 A 5/1997 Pollock et al.  
 5,637,850 A 6/1997 Honda  
 5,650,596 A 7/1997 Morris et al.  
 5,678,569 A 10/1997 Chew et al.  
 5,805,451 A 9/1998 Speas et al.  
 5,923,001 A 7/1999 Morris et al.  
 5,931,824 A 8/1999 Stewart et al.  
 5,991,728 A 11/1999 DeBusk et al.  
 6,150,948 A 11/2000 Watkins  
 6,307,473 B1 10/2001 Zampini et al.  
 6,653,937 B2 11/2003 Nelson et al.  
 7,017,800 B2 3/2006 Ulrich et al.  
 7,019,642 B2 3/2006 Nelson et al.  
 7,170,415 B2 1/2007 Forster  
 7,633,394 B2 12/2009 Forster  
 7,703,674 B2 4/2010 Stewart et al.  
 7,791,453 B2 9/2010 Chen et al.  
 8,181,860 B2 5/2012 Fleck et al.  
 8,519,823 B2 8/2013 Rinkes  
 8,593,260 B2 11/2013 Chen et al.

9,542,663 B2 1/2017 Colburn et al.  
 10,127,356 B2 11/2018 Colburn et al.  
 11,116,598 B1 9/2021 Fleck et al.  
 2002/0049650 A1 4/2002 Reff  
 2002/0070862 A1 6/2002 Francis et al.  
 2003/0196837 A1 10/2003 Ballard  
 2006/0145855 A1 7/2006 Diorio et al.  
 2006/0176152 A1 8/2006 Wagner et al.  
 2006/0197652 A1 9/2006 Hild et al.  
 2006/0238302 A1 10/2006 Loving et al.  
 2006/0238305 A1 10/2006 Loving et al.  
 2006/0244652 A1 11/2006 Tethrake et al.  
 2006/0290472 A1 12/2006 Onderko et al.  
 2007/0083170 A1 4/2007 Stewart et al.  
 2008/0051746 A1\* 2/2008 Shen-Gunther ..... A61M 16/047  
 604/362  
 2008/0100439 A1 5/2008 Rinkes  
 2008/0290995 A1 11/2008 Bruns et al.  
 2009/0021374 A1 1/2009 Stagg  
 2009/0145957 A1 6/2009 Zancola  
 2009/0160638 A1 6/2009 Jesme  
 2011/0139877 A1 6/2011 Szakelyhidi et al.  
 2012/0173440 A1 7/2012 Dehlinger et al.  
 2013/0088354 A1 4/2013 Thomas  
 2013/0181715 A1 7/2013 Biber  
 2014/0297371 A1 10/2014 Colburn et al.  
 2015/0216610 A1 8/2015 Augustine  
 2015/0324533 A1 11/2015 Colburn et al.  
 2017/0186160 A1\* 6/2017 Satish ..... A61M 5/14551  
 2018/0344429 A1 12/2018 Stewart  
 2019/0000589 A1 1/2019 Vanderwoude et al.  
 2019/0080797 A1 3/2019 Colburn et al.  
 2019/0298478 A1\* 10/2019 Aquino ..... A61B 17/3421  
 2021/0085428 A1 3/2021 Yavari et al.

FOREIGN PATENT DOCUMENTS

WO 9830166 A1 7/1998  
 WO 2006060324 A1 6/2006  
 WO 2008063710 A2 5/2008  
 WO 2009082620 A1 7/2009  
 WO 2011035277 A1 3/2011  
 WO 2011075433 A1 6/2011  
 WO 2013055616 A2 4/2013  
 WO 2015187857 A1 12/2015  
 WO 2017112051 A1 6/2017  
 WO 2018064288 A1 4/2018  
 WO 2019028334 A2 2/2019  
 WO 2019048944 A1 3/2019

OTHER PUBLICATIONS

International Search Report for Application No. PCT/US20006/040011 dated May 28, 2008, 1 page.  
 International Search Report for Application No. PCT/US2020/048383 dated Nov. 16, 2020, 3 pages.  
 Zebra Technologies Corporation, "RFD8500 Quick Start Guide", MN002225A03, Revision A, Apr. 2020, 2 pages.  
 Zebra Technologies Corporation, "RFD8500 Series Product Specification Sheet", 2020, 4 pages.  
 Zebra Technologies Corporation, "RFD8500 User Guide", MN002065A06 Revision A, Jan. 2020, 118 pages.

\* cited by examiner

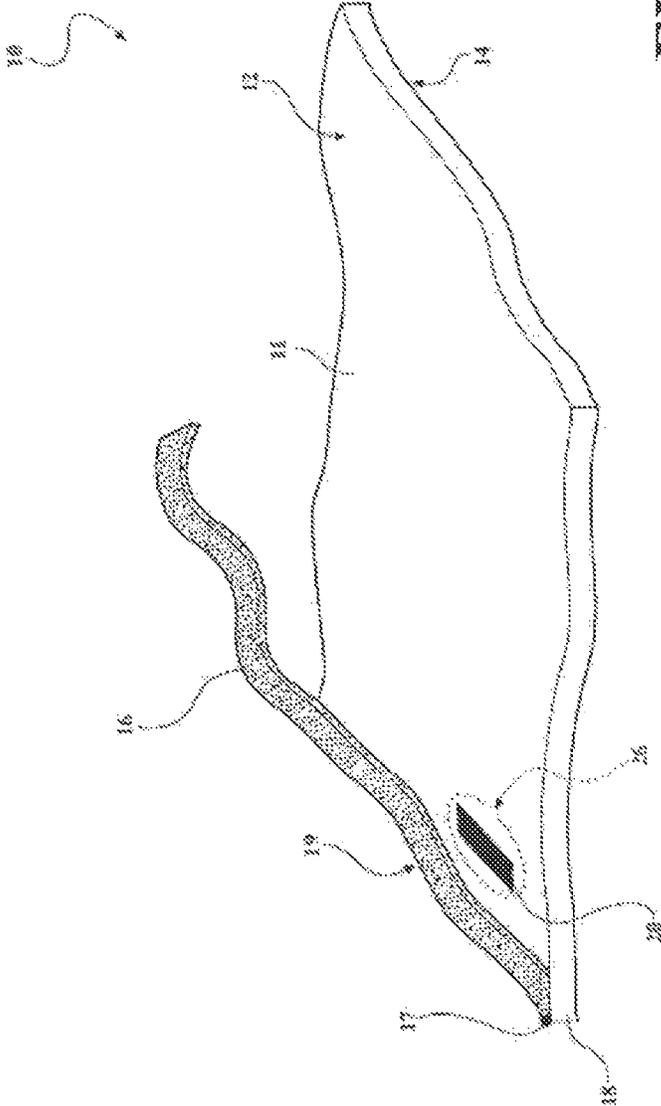
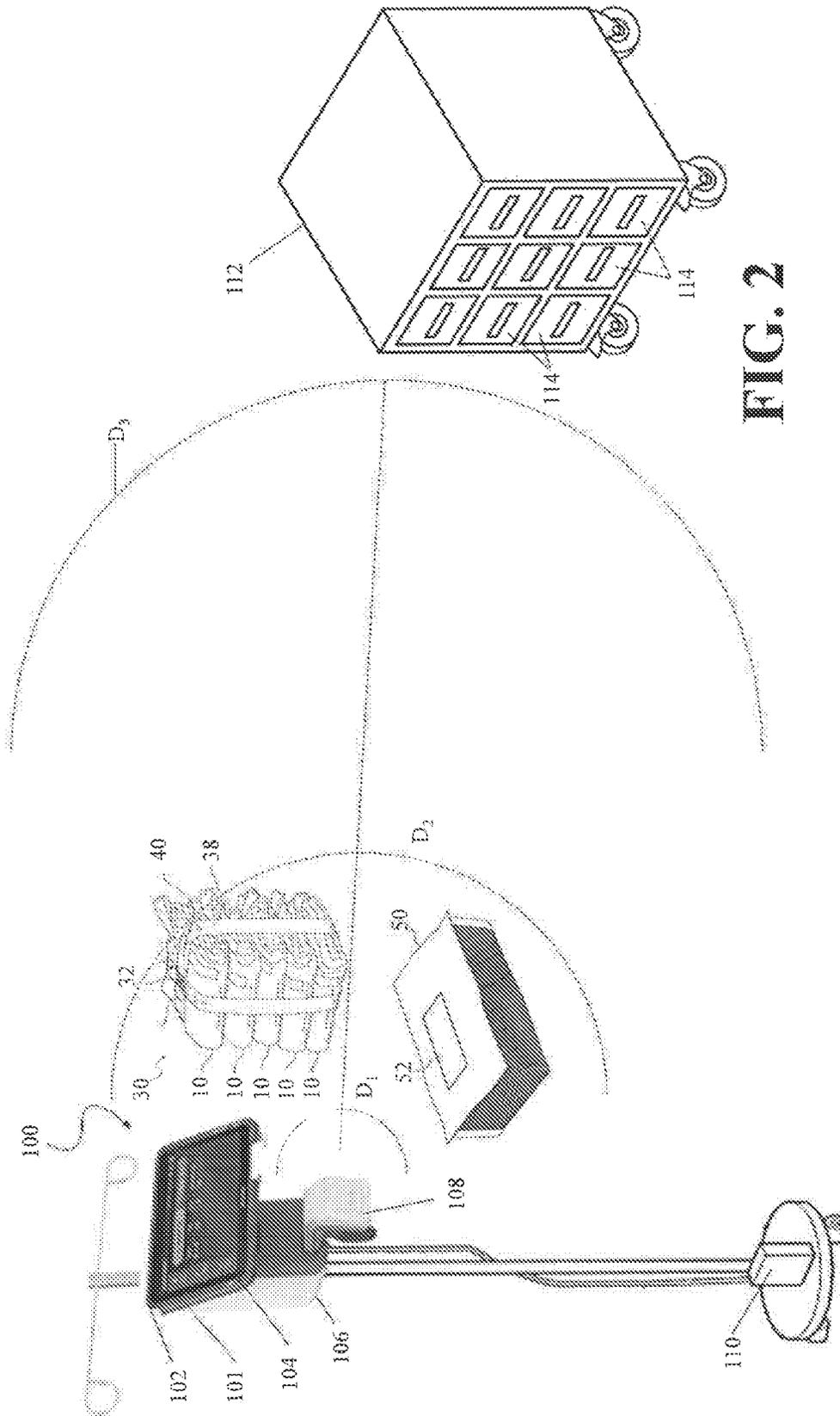


FIG. 1



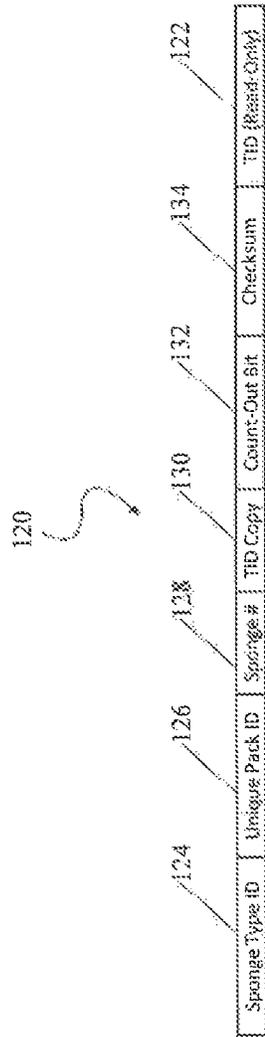


FIG. 3

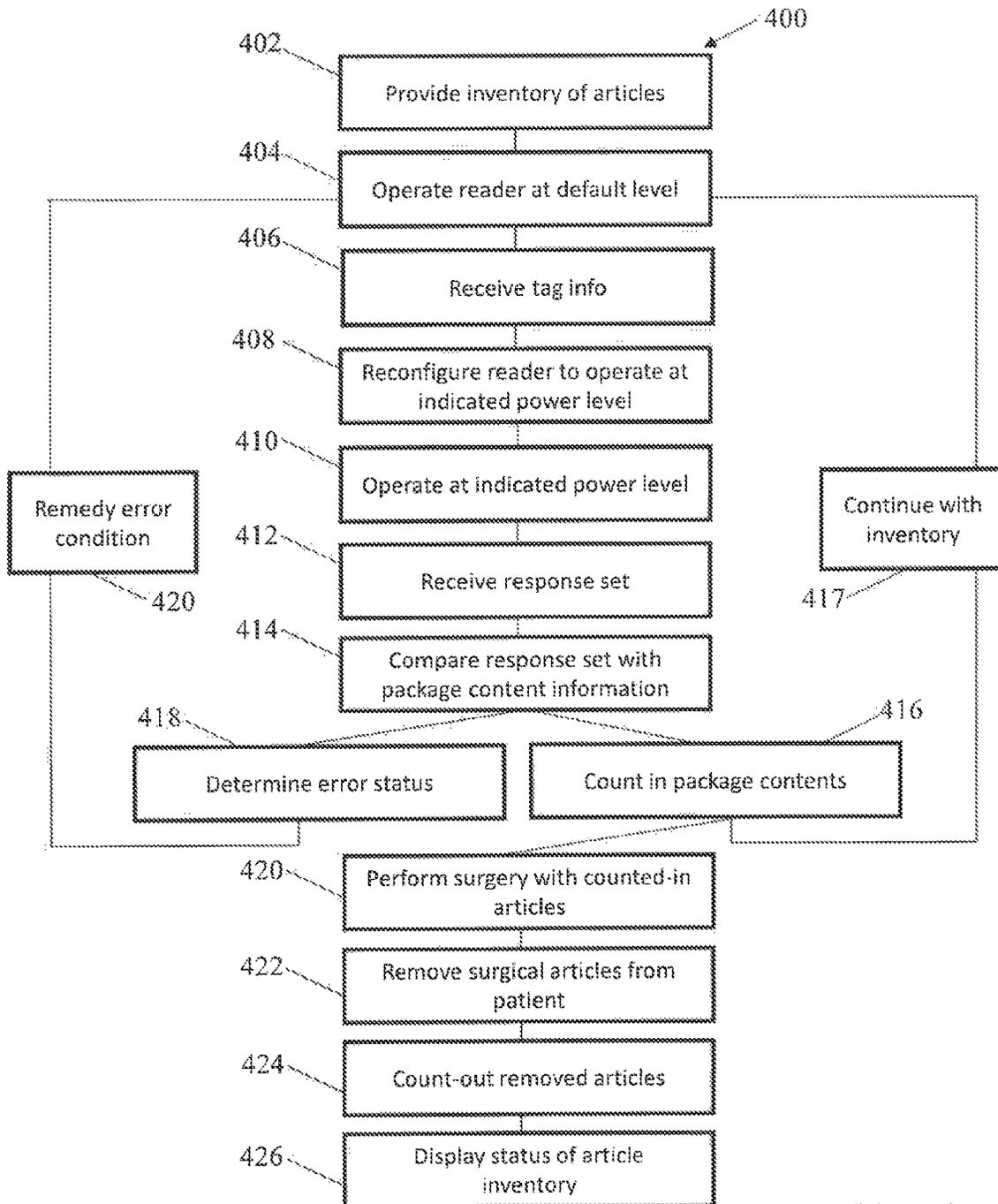


FIG. 4

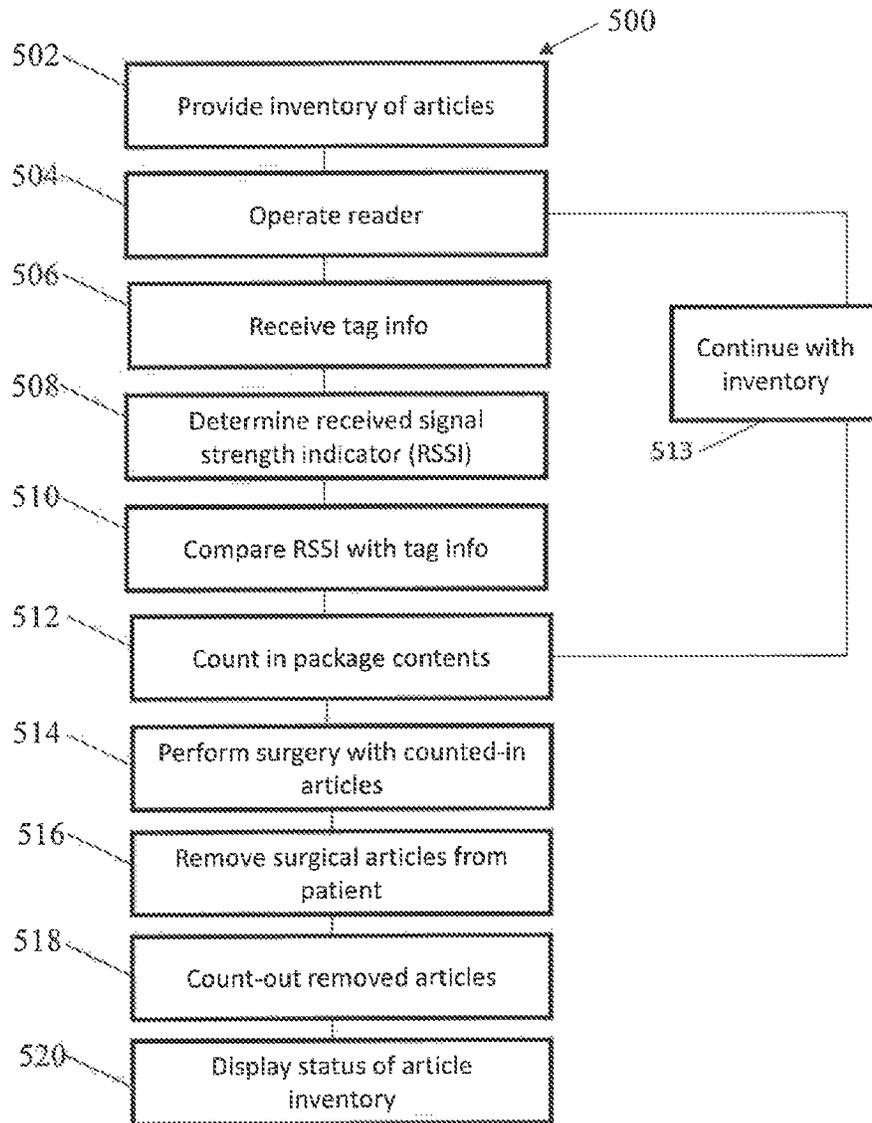


FIG. 5

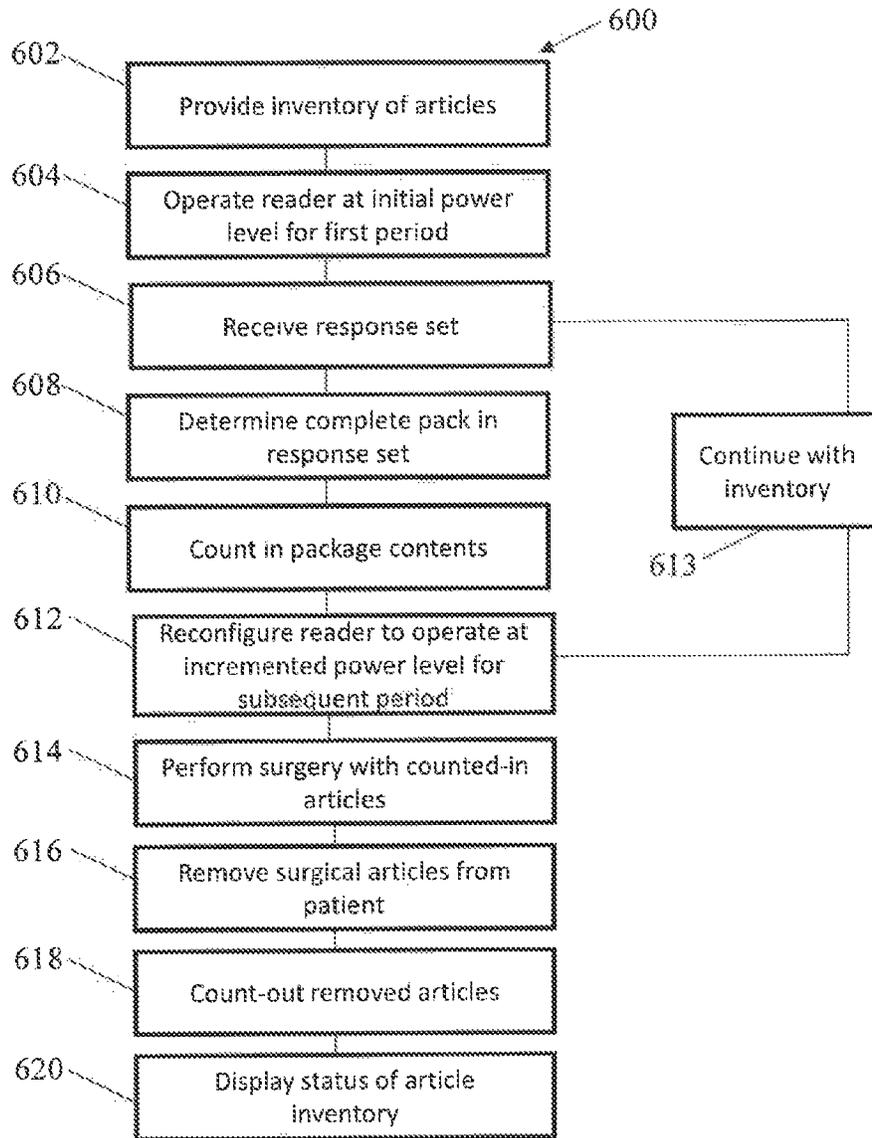


FIG. 6

## SYSTEM AND METHOD FOR MANAGING SURGICAL ARTICLES DURING A SURGICAL PROCEDURE

### REFERENCE TO RELATED APPLICATION

This application is a national entry of International Application No. PCT/US2020/048383, filed Aug. 28, 2020, which claims priority to and all the benefits of U.S. Provisional Application No. 62/894,300, filed Aug. 30, 2019, the entire contents of each are incorporated herein by reference.

### BACKGROUND

The present disclosure generally relates to systems and methods for surgical object detection and identification and, more specifically to tracking and managing RFID tagged sponges.

Before and after a surgical procedure, it is important to track the tools and surgical articles utilized during the procedure to ensure proper sterilization and disposal of the tools or articles. It is also important to have an accurate count of the tools or articles to ensure that none of the tools or articles were inadvertently lost or retained inside a patient. A surgical sponge is an example of a surgical article, which may be comprised of absorbent material for soaking up blood and other bodily fluids in and around an incision site. Health care professionals (HCPs) typically follow strict procedures to account for each and every sponge used during a surgery, in view of the risks associated with a surgical sponge being inadvertently retained inside a patient.

In the past, HCPs have relied upon counting surgical sponges by hand, however, manual counting requires handling of and exposure to soiled sponges and is prone to human error. To reduce the potential for retained surgical sponges associated with inaccurate manual counting methods, surgical sponges have been tagged with radio-opaque markers, barcodes, or wireless transponders, such as RFID or LC respondent transponders. Therefore, there is a need to provide for efficient and accurate counting of the surgical sponges to reduce or eliminate the risks associated with surgical articles being retained inside a patient.

### SUMMARY

A method of managing an inventory of surgical articles used during a surgical procedure to ensure proper accounting of surgical articles following the surgical procedure is provided. The surgical articles may be surgical sponges. The surgical articles may be implants, towels, suture needles, clips, staples, or other surgical instruments. The method includes providing an inventory of surgical sponges. The inventory includes a first package containing a first surgical sponge of a first sponge type, wherein the first surgical sponge includes a first RFID tag. The first RFID tag stores a first unique identifier associated with the first surgical sponge, first package content information, and a first power level parameter associated with the first sponge type. The first package content information corresponds to a complete content of the first package.

The method includes operating an RFID reader at a default power level and receiving at the RFID reader the first unique identifier, the first power level parameter stored in the first RFID tag, and the first package content information. The method includes reconfiguring the RFID reader to operate at a first power level, different from the default power level, corresponding to the received first power level

parameter; operating the RFID reader at the first power level; and receiving a first response set at the first power level.

The method includes comparing the first response set to the first package content information to determine an error status; and identifying the first package content information as counted-in in a database record for the surgical procedure when no error status determined. The method includes reconfiguring the RFID reader to operate at the default power level.

The method includes positioning the first surgical sponge in a body for a surgical procedure; removing the first surgical sponge from the body; and operating the RFID reader and counting-out the first surgical sponge by reading the first RFID tag with the RFID reader and updating the database record for the surgical procedure. The method includes displaying a status of the inventory of surgical sponges identifying a counted-in and counted-out status based on the database record.

In the method, the first package may further contain a plurality of surgical sponges, each surgical sponge including an associated RFID tag storing a unique identifier associated respectively with each surgical sponge in the first package, the first power level parameter. The first package content information on each RFID tag may include information to identify all other surgical sponges in the first package.

In the method, the inventory of surgical sponges may include a second package containing a second surgical sponge of a second sponge type and a third surgical sponge of the second sponge type. The second sponge type may be different from the first sponge type. The second and third surgical sponges, respectively, include a second and third RFID tags, the second RFID tag storing a second unique identifier associated with the second surgical sponge, the third RFID tag storing a third unique identifier associated with the third surgical sponge, the second and third RFID tags also storing second package content information, and a second power level parameter associated with the second sponge type, wherein the second package content information corresponds to a complete content of the second package.

The method may also include after reconfiguring the RFID reader to operate at the default power level, operating the RFID reader at the default power level, and receiving at the RFID reader one of the second and third unique identifiers, the second power level parameter, where the second power level parameter is different from the first power level parameter, and the second package content information. The method may then include reconfiguring the RFID reader to operate at the second power level; and receiving a second response set. The method then includes identifying the second and third surgical sponges as counted-in in the database record when the second and third unique identifiers are present in the second response set. The method may include comparing the second response set to the second package content information to determine an error status.

The method may also include triggering an alert when an error status is determined. Triggering the alert may include any one of sounding an alarm, displaying a warning, activating a tactile response, and combinations thereof. In the method, the error status is determined when the first result set does not match the first package content information.

The method may also include positioning the RFID reader adjacent to a sterile field in which the surgical procedure is performed; and removing the first surgical sponge from the first package after identifying the first surgical sponge as counted-in.

In the method, the steps of receiving the first response set and receiving the second response set may include, respectively, positioning the first package and the second package at a first distance and a second distance from the RFID reader, wherein the first distance is a first preferred read range for the first package and the second distance is a second preferred read range for the second package, and wherein first power level parameter and the second power level parameter are selected so that the first distance and the second distance are within a same read-in range. The preferred read-in range may be between about 12 inches and about 36 inches.

An alternative method of managing an inventory of surgical sponges used during a surgical procedure to ensure proper removal of surgical sponges following the surgical procedure is also provided. The method includes providing an inventory of surgical sponges. The inventory includes a first package containing a first surgical sponge of a first sponge type, wherein the first surgical sponge includes a first RFID tag. The first RFID tag stores a first unique identifier associated with the first surgical sponge.

The method includes operating an RFID reader to read the RFID tags of the inventory of surgical sponges; and receiving, in response to operating the RFID reader, a response signal comprising the unique identifier stored in the RFID tag. The method includes determining a first received signal strength indicator (RSSI) as a measure of a power level of the response signal from the first RFID tag when read by the RFID reader; and identifying the first surgical sponge as counted-in in a database record for the surgical procedure when the first RSSI meets a first predetermined threshold associated with the first sponge type indicated by the first unique identifier.

The method includes positioning the first surgical sponge in a body for a surgical procedure; removing the first surgical sponge from the body; and reading the first RFID tag with the RFID reader and identifying the first surgical sponge as counted-out in the database. The method includes displaying a status of the inventory of surgical sponges identifying a counted-in and counted-out status based on the database record.

In the method, the inventory of surgical sponges may comprise a second package containing a second surgical sponge of a second sponge type, the second surgical sponge comprising a second RFID tag, the second RFID tag storing a second unique identifier associated with the second surgical sponge. The method may also include determining a second RSSI from the second RFID tag; and identifying the second surgical sponge as counted-in in the database when the second RSSI meets a second predetermined threshold associated with the second sponge type indicated by the second unique identifier.

In the method, the first package may contain a single sponge per package, and the second package may contain a plurality of sponges per package. The first RSSI may be higher than the second RSSI.

The method may include positioning the first package at a first distance from the RFID reader. The first distance may be a first preferred read range for the first package. The method may include positioning the second package at a second distance from the RFID reader. The second distance may be a second preferred read range for the second package. The first predetermined threshold and the second predetermined threshold may be selected so that the first distance and the second distance are within a same read-in range. The read-in range may be between about 12 inches and about 36 inches.

A further alternative method of managing an inventory of surgical sponges used during a surgical procedure to ensure proper removal of surgical sponges following the surgical procedure is provided. The method includes providing an inventory of surgical sponges. The inventory may include a first package containing a first surgical sponge of a first sponge type. The first surgical sponge includes a first RFID tag. The first RFID tag stores a first unique identifier associated with the first surgical sponge, first package content information, and a first assigned power level associated with the first sponge type. The first package content information corresponds to a complete content of the first package.

The method includes operating an RFID reader at a first power level for a first limited period of time to read RFID tags of the inventory of surgical sponges; collecting a first response set during the first limited period of time; and evaluating the first response set to determine a complete first package when the first response set matches the first package content information such that all surgical sponges within the first package are present in the first response set. The method also includes determining whether the first power level matches the first assigned power level; and identifying the first surgical sponge as counted-in in a database record for the surgical procedure when the complete first package is determined and the first power level matches the first assigned power level. The method includes reconfiguring the RFID reader to operate at a second power level for a second limited period of time. The second power level is different from the first power level.

The method includes positioning at least one of the counted-in surgical sponges in a body for a surgical procedure; removing the counted-in surgical sponges from the body; and operating the RFID reader and counting-out the first surgical sponge by reading the first RFID tag with the RFID reader. The method includes displaying a status of the inventory of surgical sponges providing a number of counted-in and counted-out surgical sponges for each type of surgical sponge.

In the method, the inventory of surgical sponges further comprises a second package containing a second surgical sponge and a third surgical sponge, the second and third surgical sponges being of a second sponge type, wherein the second sponge comprises a second RFID tag, the second RFID tag storing a second unique identifier associated with the second surgical sponge, second package content information, and a second assigned power level associated with the second sponge type. The third sponge comprises a third RFID tag. The third RFID tag stores a third unique identifier associated with the third surgical sponge, second package content information, and a second assigned power level associated with the second sponge type. The second package content information corresponds to a complete content of the second package.

The method may also include operating an RFID reader at the power level for a second limited period of time; collecting a second response set during the second limited period of time; evaluating the second response set to determine a complete second package when the second response set matches the second package content information such that all surgical sponges within the second package are present in the second response set and to determine whether the second power level matches the second assigned power level; and identifying the second and the third surgical sponges as counted-in in the database record for the surgical procedure

when the complete second package is determined and the second power level matches the second assigned power level.

A system for managing an inventory of surgical sponges used during a surgical procedure to ensure proper removal of surgical sponges following the surgical procedure is also provided. The system includes an inventory of surgical sponges. The inventory includes a first package containing a first surgical sponge of a first sponge type. The first surgical sponge comprises a first RFID tag. The first RFID tag stores a first unique identifier associated with the first surgical sponge, first package content information, and a first power level parameter associated with the first sponge type. The first package content information corresponds to a complete content of the first package. The system also includes an RFID reader configurable to operate at one of a plurality of power levels in response to receiving a power level parameter in response to an RFID read operation.

The system includes a database configured to store data representing a status of the inventory of surgical sponges identifying a counted-in quantity and a counted-out quantity. The RFID reader is configured to operate at a default power level. The RFID reader is configured to receive the first unique identifier, the first power level parameter, and the first package content information. The RFID reader may reconfigure to operate at a first power level, different from the default power level, corresponding to the received first power level parameter; and to operate at the first power level. The RFID reader receives a first response set at the first power level and identifies the first surgical sponge as counted-in in a database record for the surgical procedure when the first unique identifier is present in the first response set; and compares the first response set to the first package content information to determine an error status. The system also includes a display device to display a status of the inventory of surgical sponges identifying a counted-in quantity and a counted-out quantity.

In the system, the inventory of surgical sponges may include a second package containing a second surgical sponge and a third surgical sponge. The second and third surgical sponges are a second sponge type. The second sponge includes a second RFID tag. The second RFID tag stores a second unique identifier associated with the second surgical sponge, the second package content information, and a second assigned power level associated with the second sponge type. The third sponge includes a third RFID tag. The third RFID tag stores a third unique identifier associated with the third surgical sponge, second package content information, and a second assigned power level associated with the second sponge type. The second package content information corresponds to a complete content of the second package.

The RFID reader is further configured to operate at the default power level; receive the second unique identifier, the second power level parameter, and the first package content information. The RFID reader reconfigures to operate at the second power level, different from the first power level, corresponding to the received second power level parameter; and operate at the second power level. The RFID reader receives a second response set at the second power level; and identifies the second and the third surgical sponges as counted-in in the database record for the surgical procedure when the second and the third unique identifiers are present in the second response set; and compares the second response set to the second package content information to determine an error status.

The RFID reader may further trigger an alert when an error status is determined. The alert may include any one of an alarm, a warning, a tactile response, and combinations thereof. The error status is determined when the first result set does not match the first package content information.

An alternative system for managing an inventory of surgical sponges used during a surgical procedure to ensure proper removal of surgical sponges following the surgical procedure is provided. The system includes an inventory of sterile surgical sponges. The inventory includes a first package containing a first surgical sponge of a first sponge type, wherein the first surgical sponge comprises a first RFID tag. The first RFID tag stores a first unique identifier associated with the first surgical sponge, first package content information, and a first power level parameter associated with the first sponge type. The first package content information corresponds to a complete content of the first package. The inventory of surgical sponges includes a second package containing a second surgical sponge and a third surgical sponge. The second and third surgical sponges are a second sponge type. The second sponge includes a second RFID tag. The second RFID tag stores a second unique identifier associated with the second surgical sponge, second package content information, and a second assigned power level associated with the second sponge type. The third sponge includes a third RFID tag. The third RFID tag stores a third unique identifier associated with the third surgical sponge, second package content information, and a second assigned power level associated with the second sponge type.

The system includes an RFID reader configurable to operate at one of a plurality of power levels in response to receiving a power level parameter in response to an RFID read operation. The system also includes a database configured to store data representing a status of the inventory of surgical sponges, identifying a counted-in quantity and a counted-out quantity.

The RFID reader is configured to read RFID tags at multiple power levels. The RFID reader is configured to count-in the first package at a first power level when the RFID reader operates at the first power level associated with the first sponge type and determines the first package is complete. The RFID reader is further configured to count-in the second package at a second power level when the RFID reader operates at the second power level, different from the first power level, the second power level associated with the second sponge type, different from the first sponge type, and determines the second package is complete.

The first power level is associated with the first sponge type so that a preferred read range of the first sponge type is between 12 inches and 36 inches from the RFID reader based on a first packaging configuration of the first sponge type; and the second power level is associated with the second sponge type so that a preferred read range of the second sponge type is also between 12 inches and 36 inches from the RFID reader based on a second packaging configuration of the second sponge type.

#### BRIEF DESCRIPTION OF THE DRAWINGS

Referring now to the drawings, exemplary illustrations are shown in detail. Although the drawings represent schematic illustrations, the drawings are not necessarily to scale, and certain features may be exaggerated to better illustrate and explain an innovative aspect of an illustrative example. Further, the exemplary illustrations described herein are not intended to be exhaustive or otherwise limiting or restricting

to the precise form and configuration shown in the drawings and disclosed in the following detailed description.

Advantages of the present disclosure will be readily appreciated as the same becomes better understood by reference to the following detailed description when considered in connection with the accompanying drawings wherein:

FIG. 1 illustrates a surgical article as a surgical sponge.

FIG. 2 illustrates an exemplary system to manage an inventory of surgical articles showing a first and second article package within a read range of an RFID reader and an inventory of surgical articles at a distance from the RFID reader;

FIG. 3 illustrates an identification scheme of information that may be stored on an RFID tag.

FIG. 4 illustrates a first method for managing surgical articles during a surgical procedure.

FIG. 5 illustrates a second method for managing surgical articles during a surgical procedure.

FIG. 6 illustrates a third method for managing surgical articles during a surgical procedure.

#### DETAILED DESCRIPTION

The present disclosure relates to systems and methods for managing an inventory of surgical articles during a surgical procedure to ensure the proper removal of the surgical articles from the patient following the surgical procedure and thereby prevent the undesirable retention of the surgical articles within the patient.

FIG. 1 illustrates one such surgical article, a surgical sponge **10**, having one or more tags for counting or detecting the surgical article before, during, or after a surgical procedure. In particular, the surgical article illustrated in FIG. 1 may comprise a surgical sponge **10** further comprising a tag **20**, as described in detail below. However, while not shown in the Figures, it has been contemplated that other alternatives of the surgical article **10** can include laparotomy pads, gauzes, implants, towels, suture needles, clips, staples, or surgical instruments. Another example of the surgical article may comprise a surgical instrument, such as a scalpel or forceps, comprising a tag **20**.

The tag **20** may comprise counting element(s), detecting element(s), or any combination thereof and may be incorporated within handles, between layers of, or other portions of the surgical article **10**. As described in detail below, each surgical article **10** can include one or more tags **20**, and each tag **20** may include various combinations of the counting elements or the detecting elements. For example, one of these tags **20** may comprise an RFID element (RFID tag). However, each tag **20** can include any number of counting elements and any number of detecting elements, in addition or in the alternative, consistent with the disclosure herein.

The tag **20** may be configured to include unique identification information for each surgical article **10**. The unique identification information may comprise a serial number or other identifier that is unique and assigned only to the corresponding article **10**. The unique identification information may further convey the type, size, weight, manufacturing dates, expiration date, number of similar articles **10** in a corresponding package, the unique identification of the articles packaged together, or other information used for counting or detecting the article **10**.

The tag **20** may convey the unique identification information by transmitting an electromagnetic signal or wave corresponding to the unique identification information. Each surgical article **10** may comprise, in addition, a second tag

(not shown) having the unique identifier or other information in a form scannable by an optical-scanning device or human-readable that can be manually entered into a user interface of the scanning device, computer, or other system.

A plurality of tags on a surgical article may be different from one another, yet include the same unique identification information related to the specific surgical article to which the tag is affixed. The tag **20** may allow an HCP to identify the number of surgical articles **10** present or to determine a location of the surgical articles **10** within the body of the patient, within an operating room, or both inside the body of the patient and within the operating room. In other alternatives, the tag(s) **20** may be detectable within the operating room but not within the body of the patient.

The tag **20** may be incorporated within handles, between layers of, or other portions of the surgical article **10**. For example, the tag **20** can be adhered to or encapsulated within the layers of the surgical article **10**, embedded within the handle, or coupled to other portions of the article **10**. Each tag **20** may be rigid to increase its service life. In other examples, the tag **20** can be flexible to permit the surgical article **10** and the tag to be folded or otherwise shaped in a more preferable manner for use within a patient's body. Furthermore, the tag **20** may be encapsulated in a biocompatible plastic coating, pouch, or housing **26** that is water-impermeable and sterilizable. The housing **26** may be coupled to the surgical article **10** via stitching, adhesive, or similar type of fastener. The counting or detecting elements of the tag **20** may be configured to cooperate with at least one detector-interrogating antenna (detecting antenna) of a reader, as a scanning device, such as a hand-held device manipulatable by the HCP. Alternatively, a detector-interrogating antenna may be incorporated into a surgical instrument tray, surgical cart, or canister. However, it is contemplated that any suitable antenna, including one integrated within the optical-scanning device can be configured to detect the detecting element included in the tag **20**. The antenna may further comprise a circuit, coil, or loop configured to define a plane of the antenna, wherein a signal, which can be carried on, or understood as, an electromagnetic field, may be transmitted outward from the plane of the antenna, to be received by the tags **20** which then provide a response signal that can be projected back to the antenna. The Applicant has described a scanning device or scanning apparatus with an antenna in U.S. Pat. No. 8,181,860, filed on Sep. 13, 2007, the disclosure of which is hereby incorporated by reference.

A wide variety of tags may be commercially available by a number of manufacturers. Certain tags may be configured to provide significant amounts of user accessible memory, sometimes in the form of read-only memory or write-once memory. One exemplary tag is an RFID tag **20** detectable by a RFID antenna. However, it is contemplated that the surgical article **10** can include any suitable tag detectable by any corresponding detecting antenna. The Applicant has described a surgical article **10** and method of managing surgical articles that comprise various tags in PCT Application No. PCT/US2016/057077, filed on Oct. 14, 2016, the disclosure of which is hereby incorporated by reference.

The surgical article may comprise a surgical sponge **10** comprising an absorbent material body **11**. The absorbent material body **11** of the surgical sponge **10** may comprise a top surface **12** and an opposing bottom surface **14**. The surgical sponge **10** may further comprise a lead, handle or string **16**. The lead **16** may comprise a radio opaque marker material that is configured to show up in a medical scan. For example, the lead may comprise a radio opaque marker

material configured to show up in an MRI image to allow for identification of a surgical sponge **10** that was inadvertently retained within a patient.

It may be important for HCPs to track surgical sponges **10** before, during, and after a surgical procedure to ensure that a surgical sponge **10** is not inadvertently retained or left within a patient. Therefore, as described above, an RFID tag **20** may be utilized to identify the location and number of sponges used in a surgical procedure. An RFID tag **20** may be coupled to the top surface of the absorbent material body **11** proximate to an edge or corner of the surgical sponge **10**. While not shown in the Figures, it is contemplated that the RFID tag **20** may be incorporated into the handle, between layers of the absorbent material or other portions of the surgical sponge **10** in any number of ways. For example, the RFID tag **20** can be adhered to or embedded within the handle or coupled to other portions of the surgical sponge **10**.

The detecting element of the RFID tag **20** may be used with a multiplex detection system. The RFID tag **20** can include a capacitor and an antenna (not shown), which receives power from the detecting antenna (RFID antenna) of the reader to charge the capacitor of the RFID tag **20**. This capacitor becomes the power source for the operation of an unpowered RFID tag **20**. The RFID tag **20** can have an integrated circuit, which includes a reading function, a carrier frequency modulating function, and a read-only memory portion with a burned-in code. The integrated circuit and corresponding antenna of the detecting element are encapsulated in an enclosure that is resistant to blood, water, or saline solution. Thus, the RFID tag **20** can withstand repeated sterilization and be attached to other surgical articles, such as metal instruments, which are sterilized and reused multiple times. Depending on the carrier frequency and the type of RFID tag **20**, the RFID tag **20** can vary significantly in cost, size, and resistance to shielding by intervening tissue.

One feature provided by RFID based technology is that the RFID tag **20** achieves the dual purpose of detecting the location of the surgical sponge **10** in addition to counting or identifying the surgical sponge **10**. Thus, certain RFID tags **20** may serve as both detection elements and counting elements. The RFID tag cooperates with the detecting antenna of the reader to both detect the location of the surgical sponge **10** and provide data for determining the unique identification information of the surgical sponge **10**. The RFID tags **20** may operate above the MHz range. Exemplary frequencies can include about 13.35 to 14.15 MHz (high frequency), a range from 850 to 950 MHz (ultra-high frequency), or a range of microwave frequencies (i.e., 2.45 to 2.55 GHz). The added bandwidth provided by these RFID tags **20** can increase the probability of detecting and finding the corresponding surgical sponge **10** within the interrogation zone and within a short period of time.

Turning now to FIG. 2, a system for detecting, identifying and managing an inventory of surgical objects during a surgical operation is disclosed. The scanning device may be configured to maintain a record of the surgical articles **10** used in the procedure in on-board memory, or in cooperation with a server. The scanning device includes an RFID interrogator in communication with the on-board memory. The RFID interrogator includes the physical components and the operating software for generating and receiving the radio frequency signals. Among the physical components of the interrogator are the radio controller, including a signal-generating transmitter, a signal receiver, or a transceiver.

The record of the surgical articles created and maintained by the system may be stored on the scanning device in on-board memory, or else the record may be communicated to a server for storage. The scanning device may have a wired or a wireless connection to the server. In some alternatives, there may be one or more devices disposed in communication between the scanning device and the server. In one example, the scanning device within an operating room may communicate with a computer located in the operating room that is in further communication with other medical devices and tools in the operating room. The computer may communicate information to a router that acts as a gateway to a network. The server is also connected to the network, and thus the scanning device communicates with the server through multiple layers of devices.

At the conclusion of the surgical procedure, the records can be transmitted to a server and matched with patient records, such as electronic medical records, to update the same and provide an indication of which specific surgical articles were used with each patient at which times.

In FIG. 2 examples of various containers for packaging or bundling two or more surgical sponges **10** are shown. A strap **38** or plurality of straps **38** may be utilized to bundle or package two or more surgical sponges **10** together. The strap(s) **38** may be configured to bundle the two or more surgical sponges **10** to maintain a defined relationship between the RFID tags **20** of adjacent surgical sponges **10** in the bundle **30**. For example, a plurality of surgical sponges **10** may be stacked on top of one another and packaged together by a strap or band **38**. The strap **38** may be configured to bundle **2, 3, 5, 10, 20**, or more surgical sponges **10** together. Alternatively, one, or two or more surgical sponges **10** may be packaged or bundled within a pouch or container **50**. The container **50** may be similarly configured to the strap, wherein the container **50** is configured to maintain a defined relationship between the RFID tags **20** of adjacent surgical sponges **10** in the container **50**. The container **50** may comprise a poly-Tyvek® pouch, a rigid base with a poly-Tyvek® cover, or similar containment apparatus. Any number of surgical sponges **10**, or surgical instruments may be packaged or bundled by the strap **38** or within the container **50**.

Bundling or packaging surgical sponges **10** as described above can create challenges for scanning the RFID tag(s) **20** of the individual surgical sponges **10** included in the bundle **30**. When attempting to scan the RFID tag **20** of the surgical sponges **10** when packaged, one potential challenge is that there is an increased possibility of interference between the RFID tags **20** that may result in an inaccurate count or reduced detection distance of the surgical sponges **10**. Providing a sufficient detection distance is important for surgical tools and articles because the sterility of the surgical tools and articles needs to be maintained and the RFID reader may not be sterile or available within the sterile field. If the read distance is insufficient the HCP will need to spend additional time and incur additional costs to sterilely drape the scanner prior to each surgery. On the other hand, simply increasing the scanner power output to overcome the challenges of densely packaged RFID-tagged surgical articles may result in the undesirable counting-in of surgical sponges being transported or stored nearby, including in adjacent operating rooms or other storage locations. Accidental count-in of surgical articles not intended for the active surgical procedure may cause HCPs to waste time and extend the length of a surgical procedure while attempts are made to account for surgical articles never intended to be used in the procedure.

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A system **100** for managing surgical articles during a surgical procedure is illustrated in FIG. 2. The system **100** includes the hardware and software to communicate with RFID-tagged surgical articles, create and maintain database records managing an inventory of the surgical articles, including identifying type number, type, and unique identification of those surgical articles made available for use in a particular surgical procedure. The system **100** provides the interface for an HCP to enter information into the database, and to access that information and other information in the database before, during and after a surgical operation.

The system **100** includes a system computer **101** in communication with a display **102**. The display **102** may be an integrated display, such as a tablet computer that further includes a touchscreen **104**, or other input hardware (not shown). In other alternatives the display **102** may simply be a monitor with the system computer **101** and input functionality provided by other hardware in communication with the display **102**. Other input hardware (not shown) may include a microphone for voice command control, or a video camera or other sensor to provide gesture control. Further alternative input hardware may include a trackball, touchpad, keyboard, mouse, or the like.

The display **102** may be supported on a base **106**. The base **106** may be pole mounted, as illustrated in FIG. 2. In other alternatives, the base **106** may be a mobile cart, or a stationary unit. The base **106** may be a mechanical support for the display **102** as an integrated display including the power source, computing and input functionality all in the display itself, such as a tablet computer. Alternatively, the base **106** may support functions that are not integrated within the display **102**. For example, the base **106** may include the system computer **101**, and a rechargeable battery to provide power to the system **100**, including providing power to the display **102**. The base **106** may house a central processing unit, memory device, data storage device, other hardware for the system computer **101**.

The base **106** may also support a RFID reader **108** in communication with the system computer **101**. The RFID reader **108** may be integrated into the base **106** or may be removable and operate remotely from the base **106**. The base **106** may provide a dock for a removeable, mobile RFID reader, such as a hand-held RFID reader **108**. When docked in base **106**, the RFID reader may rely on a power source external to itself and may use wired dock connections for communication with the system computer **101**.

The RFID reader may include an RFID transceiver enabling communication between the RFID reader **108** and an RFID tag, such as tag **20** of surgical sponge **10**. The RFID reader **108** may include its own power source, data processing, and memory or data storage devices internal to the RFID reader **108**. The RFID reader **108** may be configurable to operate with varying levels of power provided to the RFID transceiver to change the effective output of radio energy from the antenna.

The system **100** may include or be in communication with an external computing device **110**. This may include additional memory or data storage. The device **110** may provide wireless connectivity of other systems, such as a router or modem to communicate with remote resources, such as a hospital network or internet server. In other alternatives, network connectivity is integrated into the system computer **101** without the need for an external device **110**.

The system **100** may be provided within a surgical environment such as a hospital operating room. The system **100** may be adapted to be draped for positioning in the sterile field. Alternatively, the system **100** may be positioned adja-

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cent to but outside of the sterile field to avoid the need for sterile draping. In further alternatives, the base **106** may be positioned outside of the sterile field, but the mobile RFID reader **108** may be separate from the base **106** and enter into the sterile field with appropriate sterile draping or other sterilization-maintaining measures as may be known in the art.

The system **100** may be provided with an inventory **112** of surgical articles tagged with RFID tags to be managed during the surgical procedure. In FIG. 2, the inventory of surgical articles is illustrated as a mobile cabinet or cart with drawers **114** containing the supply of a number of different types of RFID tagged surgical articles, such as surgical sponge **10**. As described above, surgical sponges **10** may be packaged or bundled in various quantities. RFID-tagged surgical sponges **10** come in a variety of shapes from as small as 2 inches by 2 inches to as large as 8 inches by 108 inches. There are also thickness variations in the number of layers that make up a single surgical sponge **10**. For example, some surgical sponges **10** may be as few as 4 ply or as many as 32 ply. Most commonly, surgical sponges **10** are packaged from singly in a package up to 10 units within a package.

Each of the surgical articles, e.g., surgical sponges **10**, is tagged with an RFID tag, e.g., tag **20**, containing data to uniquely identify the individual item as well as provide other information relevant to manage an inventory of surgical articles. Referring now to FIG. 3, an exemplary identification scheme **120** that may be stored in the RFID tag **20** is shown. A variety of tags and data encoding schemes are presently available and the description of the identification scheme **120** is not intended to be limiting. Generally, RFID tags will be manufactured with a tag identification (TID) **122** assigned by the manufacturer of the RFID integrated circuit (IC). This TID **122** is typically stored in a write-once memory location, otherwise known as a read-only memory location on the IC. In addition to the TID **122** provided by the tag manufacturer, other information may be provided in connection with associating the tag IC to a particular surgical article, such as surgical sponge **10**.

The identification scheme **120** may include a portion **124** dedicated to identifying the type of surgical article to which the tag is affixed, i.e., sponge type ID. In one alternative, the sponge type ID **124**, as described above is a value which may be used by the system computer **101** in combination with a look-up table to retrieve further specification information relevant to the sponge type, such as quantity of sponges for that sponge type, name to be displayed on the user-interface, a designated power level for the RFID reader to operate at while counting-in sponges of that type. The look-up table may be stored local to the system computer **101**, such as in data storage of an integrated display **102**, data storage provided in the base **106**, data storage of an external computer device **110**, or remotely from the system computer **101**, such as on a hospital network or internet server location. In other alternatives, the sponge type ID **124** may be encoded to provide certain information directly, rather than requiring correlation to a look-up table value. For example, the sponge type ID **124** may correspond directly to a designated RFID reader power level associated with the particular type of sponge. In either case, the sponge type ID **124** may correspond to a power level parameter stored on the RFID tag associated with the sponge type. The power level parameter may directly encode a power level value in dBm, or may otherwise provide data corresponding to a power, current, voltage, or other setting for the reader in controlling or modulating power output, directly or indirectly, from the

antenna of the reader. In other alternatives, the sponge type ID **124** may be correlated to or encoded with an RSSI threshold associated to the sponge type and a minimum read strength for counting-in the surgical article to the surgical procedure, as described in greater detail below.

The identification scheme **120** may include information serving to identify the package of sponges, how many sponges are in a package and where a particular sponge falls within that quantity. For example, the identification scheme may include a unique package ID **126** and a sponge number **128**. Each package of sponges may be assigned a unique identification that will be shared by all members common to a single package. The unique package ID **126** may also be encoded such that certain values within the unique package ID serve to identify or designate the package as being of a particular type of surgical article. The unique package ID **126** may also be encoded such that certain values identify the quantity of sponges within the package. For each sponge **10** in a package, the sponge number **128** differentiates it from the other sponges in the package. For example, in a package of ten sponges **10**, there is one sponge with sponge number **128** of 1, one sponge with 2, and so on up to sponge number **128** of 10. Together, the unique package ID **126** and the sponge number **128** may represent package content information stored on the tag.

The identification scheme **120** may include a copy **130** of the read-only TID in the rewritable memory as a security measure to ensure that the written data has been uniquely assigned and not copied from a previous tag. The TID copy **130**, either alone, or in combination with other data stored on the tag may serve as a unique identifier to uniquely identify the sponge to which the tag is affixed. As a further potential security measure, or a way to ensure that the data has not been corrupted, in the identification scheme **120** is the checksum **134**. All or a portion of the data contained in the identification scheme on a tag **120** may be used as an input for a mathematical algorithm to generate a checksum value. The particular mathematical algorithm may be proprietary to the sponge manufacturer to ensure that its tags are uniquely identifying only first-party produced sponges, or sponges produced by an otherwise authorized party. A simple example of such an algorithm may be to sum all the values in the other data fields of the identification scheme **120**, divide the sum by a given constant, and use the remainder as the checksum value. Without knowing the particular constant used in the algorithm, unauthorized products may be detected by the system computer **101** as a step of the count-in process where the tag data is verified for authenticity.

The identification scheme **120** may include a provision to write to the tag in the course of the count-in or count-out process. For example, identification scheme **120** in FIG. 3 includes the count-out bit **132** which is a flag that is toggled after a sponge has been counted-out. This toggle may be accomplished, for example, by sending instructions from the RFID reader operating in a count-out mode instructing the tag to change the value of this data field upon being counted-out at a conclusion of a surgical procedure. This value may be particularly advantageous in an emergency situation where RFID-tagged sponges are used with a patient without completing the normal count-in procedure. The count-out bit **132** is a value toggled during the process and may be used by the system computer **101** in correctly managing the inventory of surgical articles during a surgical procedure.

The system **100** manages the inventory of surgical articles during a surgical procedure based on the information stored

on the RFID tags of the surgical articles, such as surgical sponges **10** and RFID tags **20**. The system **100** may include a database of records storing information necessary to manage the inventory of surgical articles, specifically identifying the counted-in and counted-out status of surgical articles associated with particular surgical procedures. In particular, the system **100** may be configured to count-in the surgical articles at the beginning of a surgical procedure by scanning the articles with the RFID reader **108**, and to count-out the surgical articles at the end of the procedure. To overcome the challenges of variable package quantities and different types of surgical articles, e.g., different sizes of sponges in one package versus another, that may be used within a surgical procedure, the RFID reader **108** may be configured to operate with a dynamic power level based on a power level parameter stored on the tag or retrieved from a look-up table based on data stored on the tag.

More specifically, the system **100** may operate the RFID reader **108** first at a default power level. This default power level may represent a mid-range value within the full scope of capability of the RFID reader **108**. Alternatively, the default power level may be a high extreme or low extreme value depending on the desired first read result set. For example, in an environment with close proximity to storage, such as where the base **106** is mounted to an extension of inventory cabinet **112**, it may be desirable to set the default power level to a low extreme value of the RFID reader's **108** capability. In this way, the system **100** will not be overwhelmed with an over expansive result set. In an alternative, it may be desirable to set the default power level to a high extreme value of the RFID reader's **108** capability where the system **100** is disposed at a greater distance from an inventory storage location and from the sterile field where the surgical procedure will occur. Another consideration may be the amount of ambient electromagnetic noise in the environment that may interfere with the consistent communication between the RFID tags **20** and the RFID reader **108**.

The system **100** may evaluate the strength of the response signal received from a particular tag and assign an indicator reflective of the strength of the received response. In other words, the system **100** reports the power level of the tag's backscattered response signal in relation to the power level of the RFID reader's initial transmission signal. The response signal strength indicator or RSSI may be used to evaluate the quality of a particular tag's response within the reading zone of the RFID reader.

Operating the RFID reader **108** at the default power level, the system **100** receives in response output signals from the RFID tags **20** within the effective range of the RFID reader **108**. In one configuration, included within these signals are the unique identifiers, the power level parameters and the package content information for the surgical articles to which the RFID tags **20** are attached. The system **100** may select a first such response and reconfigure the RFID reader **108** to operate at the power level parameter of the first such response, which is different from the default power level. Once reconfigured, the system **100** operates the RFID reader **108** at the first power level to receive a first response set at the first power level. Within the first response set are the unique identifiers, the package content information and the power level parameters for all the RFID tags **20** responding to the RFID reader's **108** operation at the first power level. Comparing the first response set to the package content information from the first response selected in response to operating the RFID reader at the default power level, the system **100** is able to determine whether a complete first package is present to be checked-in to the surgical procedure

or else to determine an error status. This sequence of steps may be repeated until all desired surgical articles have been counted-in for a particular surgical procedure.

In one alternative, for a particular RFID reader power, the system 100 may be configured to count-in only those tagged articles providing a strong enough response signal relative to the RSSI associated with the sponge type. For example, operating the RFID reader at a particular power level may yield a large number of responses representing nearby stored articles. Requiring a minimum RSSI for counting-in a surgical article helps to ensure that only those surgical articles specifically presented to the RFID reader for counting-in will be counted in and actually made available for the surgical procedure, and other nearby articles are not unintentionally included.

It may be important to check the completeness of the package during the check-in process to avoid confusion for the HCP and ensure that the proper and expected quantities and types of sponges are present for the surgical procedure. The system 100, in comparing the first response set to the first package content information, is verifying that all of the expected surgical articles are actually present. For example, in selecting the first response and reconfiguring to the associated first power level parameter, the system 100 is configured to determine an error status if fewer than all the packaged contents are present when interrogated at the power level parameter designated for that sponge type. The power level parameter is specifically arranged for a particular sponge type depending on the packaging configuration—such as, how many sponges are in a packaging, as well as the size and thickness of materials that may interfere with the effective communication of the radio signals. Specifically, the power level parameter for a sponge type is selected in order to maintain a preferred read distance greater than a first distance  $D_1$  and less than a second distance  $D_2$  between the RFID reader 108 and the package of surgical articles being presented for counting-in. In a first example, the space defined between the first distance  $D_1$  and the second distance  $D_2$  constitutes the preferred read range the surgical articles at a distance from the reader to maintain their sterile condition, and otherwise to minimize the impact of any quantity of sponges stored in proximity to the system 100, accounting for differences in packaging or manipulation by the HCP. In one example, the first preferred distance  $D_1$  is about 12 inches and the second preferred distance  $D_2$  is 36 inches measured from the RFID reader.

It should be appreciated that the read range of the RFID reader 108 begins at a zero distance away from the RFID reader 108. A RFID tag placed immediately adjacent to the RFID reader 108 would be responsive to an interrogation at that distance and thus could be read by the RFID reader 108. Differences in packaging density, i.e., how many articles are in a package, potential interference by the article materials, and how the article or package is held by the HCP, are all factors that may affect the response signal quality and thus read reliability. However, placing the surgical articles immediately adjacent to the RFID reader may compromise the sterility of the surgical article. Thus, it is preferable to establish a preferred read range far enough away from the RFID reader to maintain product sterility, but not so far away as to induce responses from surgical articles that are merely stored nearby.

These measurements are merely illustrative and are not intended to be limiting. In other examples, other distances are contemplated for the first and second distances to maintain sterility of the surgical articles and minimize the impact other environmental conditions. For example, the

inventory of stored sponges is located at a greater distance  $D_3$  than the max preferred read-in distance  $D_2$ , and thus is intended to be outside the effective read range of the RFID reader 108 during the count-in process.

An exemplary table of sponge types (given, for example, in square dimensions and ply where applicable), the number of that type of sponge within a single package, and an associated power level parameter, corresponding to the effective power output at the antenna of the RFID reader 108, is presented below.

Package type	Quantity in package	Power, dBm
18 × 18	5	14
8 × 36	5	14
12 × 12	5	14
4 × 18	5	14
17 × 26 Towels	5	14
4 × 4-16ply	10	16
4 × 4-32ply	10	16
2 × 2	10	25
8 × 36	1	10
4 × 18	1	10
8 × 108	1	10
2 × 36	1	11
2 × 72	1	11
8 × 4-12ply	10	18
8 × 4-16ply	10	18
8 × 4-24ply	10	18
18 × 36	3	14

As detailed in the table, the range of power levels associated with the different packages ranges from 10 dBm to 25 dBm. The power unit dBm (otherwise expressed as  $dB_{mW}$ ) is a unit of level used to indicate a power ratio expressed in decibels (dB) with reference to one milliwatt (mW). The range of package quantities may be between 1 sponge and 10 sponges within a single package, although other quantities are contemplated within the scope of this disclosure. Assuming all else is constant, the more sponges in a package, the higher the associated power level parameter is for the associated sponge type. Packages with only 1 sponge have lower power level parameters. The size of the sponges in a package may affect the power level for the package in addition to considering the number of sponges in the package. For example, several packages are presented in the table above with a quantity of 1 per package, but those sponges with more material—that is, a larger size—are typically associated with a lower power level. In this way, the system 100 effectively manages the inventory of surgical articles during a surgical procedure, avoiding the inadvertent counting-in of nearby stored surgical articles.

It should also be noted that the table above provides illustrative examples of package types by the primary dimensions of the sponges in the package and the quantity of that type of sponge in a single package. This table is not intended to be limiting, and other sizes, quantities, or types of surgical articles are likewise contemplated by the present disclosure.

The power level associated with a particular package type may be determined empirically. For example, to determine a power level for a particular package type and quantity, an example package of that type and quantity may be scanned at a variety of power levels, in a variety of environmental conditions (i.e. in the presence of differing quantities and locations of articles stored in a relative proximity to the scanner), using a factorial design of experiments. The result sets across the different conditions may be evaluated and the

result set that provides the highest confidence of reading all articles in the package while minimizing the impact of environmental noise on the successful read of the package contents. It is further contemplated that other methods of determining the preferred power level may also be employed.

In connection with managing the inventory of surgical articles, the system **100** includes the display **102** to communicate the status of the inventory of surgical articles to the HCP. Specifically, the system **100** may display information identifying the types of surgical articles that have been counted-in and the quantity thereof, as well as the quantity of surgical articles that have been counted-out once the article has been removed from the surgical procedure.

The system **100** may also be configured to alert the HCP on the determination of an error status, such as where fewer than all of the quantity of sponges within a package appear in a result set when the RFID reader is configured to operate at a power level parameter corresponding to that article type. The system **100** may display information about the error on the display **102**, such as identifying the type of sponge presented, the number counted as present, the number expected within the package, and the discrepancy between the two. The system **100** may, in the alternative or in addition, accompany this alert display with audible alarms, visual alerts such as flashing lights. The system **100** may also activate a tactile response, for example, within the mobile RFID reader **108** if the reader **108** is undocked from the base **106**. The tactile response may include a vibration pulse or pattern of pulses.

In an alternative, the bundle **30** may comprise a master tag **32** that may include unique identification information. For example, the master tag **32** may include the number of surgical sponges **10** included in the bundle **30**, as well as include the unique identification information for each of the sponges **10** contained in the bundle **30**. The master tag **32** may include a unique identification of the package in addition to the unique identifications of the sponges within the bundle **30**.

The master tag **32** may be configured to identify the side of bundle **30** or package/object that should be scanned based on the position of the RFID tags **20**. For example, the master tag **32** or the packaging **38** may include an indicator **40** to facilitate such placement/orientation, such as an arrow pointing to the side of the bundle **30** that should be scanned for optimal accuracy. Alternatively, an indicator **40** could be placed on the side of the bundle that should be placed closest to the scanner. The indicator **40** may be placed on one or multiple sides of the bundle of sponges **30**. The indicator **40** may be placed on any side/face of the bundle.

A container **50** configured to hold an individual sponge, a plurality of sponges, a bundle **30** or plurality of bundles **30** and may comprise a similar master tag **52** configured to identify the contents of the container **50**. For example, the container master tag **52** may identify the contents of the container **50**, such as the number of sponges, or number of bundles **30** included in the container **50**, as well as any additional equipment or medical instruments included in the container **50**. A container **50** configured to hold a bundle of surgical sponges **30** may comprise a similar indicator configured to identify optimal scanning orientation/position/movement as described above with regard to indicator **40**. A master tag **32**, **52** may be provided associated with a bundle **30** or container **50** and may provide human readable, or machine-readable information, for example, an RFID tag, bar code, QR code or the like. The master tag **32**, **52** may provide additional information or identical information as

provided on the article tags, such as RFID tag **20**. The master tag **32**, **52** may be useful in performing additional verifications prior to using the articles in a surgical operation.

A first method **400** of managing an inventory of surgical articles used during a surgical procedure is illustrated. The surgical articles may be surgical sponges **10**, as described above. Implementing the described method **400** assists HCPs in ensuring the proper removal of surgical articles following the surgical procedure. The method includes a first step **402** of providing an inventory of surgical articles, such as surgical sponges. The inventory may be stored in a container, such as the mobile cabinet **112** shown in FIG. **2**. The inventory includes the packages of surgical articles. In a first example, the inventory includes at least a first package containing at least a first surgical sponge of a first sponge type. The first surgical sponge includes a first RFID tag storing a first unique identifier associated with the sponge, first package content information, and a first power level parameter associated with the first sponge type. The first package content information corresponds to a complete content of the first package. The use of designations of "first," or "second" refer only to separate iterations of the count-in method steps and are not intended to be limiting or to require that "first" is different from "second" except where specifically denoted.

As described above, the package may include more than a single article, such as quantities of 2, 3, 5, 10, 20 or more within a single package. The unique identifier may be a single memory data field of an identification scheme stored on the RFID tag or may combine entries of multiple data fields to constitute a single unique identifier. The package content information includes such information necessary to identify the unique package and the content of the package, such as quantity. In one example, the package content information relates to the unique package ID **126** of the identification scheme **120**, and may include sponge type ID **124**, to retrieve the complete package quantity, and the sponge number **128** identifying which position in the package a particular sponge occupies among the complete quantity.

The method includes a second step **404** of operating an RFID reader at a default power level. The step of operating the RFID reader refers to activating the emission of radio energy to elicit a response for the RFID tags within a range of the RFID reader. To initiate this step, an HCP may provide an input to the RFID reader either directly or through some other connected piece of hardware. The default power level denotes a power level setting of the reader which is not necessarily associated with a particular sponge type. For example, the default power level may represent a midrange of the capability of the RFID reader. Alternatively, the default power level may represent a midrange of the power level parameters associated with the different sponge types which the RFID reader is adapted to read. In one example, a default power level parameter may be 15 dBm. In other alternatives, the default power level may be selected to be one of a maximum or minimum extreme of a capable range of the RFID reader depending on the particular environment in which the RFID reader will be operated, or other considerations as described above.

The method includes the step **406** of receiving, at the RFID reader, a response or responses to operating the RFID reader at the default power level. This step may include the HCP specifically presenting a package of RFID-tagged surgical articles to the RFID reader, or vice versa, positioning them so that the RFID reader is within an effective read range of the RFID reader. The preferred read range may be

between 12 inches and 36 inches. The response to step 404 may include one or more tag data. For example, in an environment where multiple RFID tags are present, the RFID reader may employ anti-collision features or read, collect, and process multiple tag's data in one read operation. For example, such anti-collision features are described in the industry standard ISO/IEC 15693-3:2009—Anticollision and Transmission Protocol. The RFID reader is in communication with or incorporates a computer processing device to execute the operations of the method. Information may be retained in a database stored on a memory of the RFID reader, of another computer processing device, or may be distributed among multiple computer processing devices. The description of any processing or computing step may be performed by the RFID reader, or another device which is in communication with the RFID reader.

Among the response data received, a first tag's data is used for continuing the steps of the method 400, the first tag's data including a first unique identifier, the first power level parameter stored in the first RFID tag, and the first package content information for the first tag. The data upon which to continue the method 400 from this step 406, may be the first complete data received in the response time. Alternatively, the response of step 406 may prioritize the use of some types of sponges over other types of sponges or may use other criteria to designate or select a particular sponge to proceed with the steps of the method 400 in order. In one example, the response data received at the default power level may be evaluated to determine whether multiple sponges from a single package are present in the response set. If a minimum percentage of sponges from a single package are present in the response data, the first tag for continuing the steps of the method 400 may be selected from the package having at least the minimum percentage present in the response set. The minimum percentage may be between about 25% to about 50% of the sponges in a complete package. The minimum percentage may be at least 30% of the sponges in a complete package.

Based on the first RFID tag data, the method 400 includes the step 408 of reconfiguring the RFID reader to operate according to the first power level parameter, which corresponds to the first sponge type; and the step 410 of operating the RFID reader at the first power level. This operation constitutes a second interrogation by the RFID reader, but at a different power level from the default power level. The first power level may be higher or lower than the default power level, and this may return more or fewer responsive tags. Where the first power level is higher than the default power level, such as with a sponge type more densely packed with multiple sponges in a single package, more responsive tags may be found as the higher-powered interrogation overcomes the interference caused by the close proximity of the multiple tags. Where the first power level is lower than the default power level, such as with a sponge type packaged singly to a package, fewer responsive tags may be found as the effective read range will be diminished to a closer range. Thus, the method 400 includes step 412 of receiving a first response set at the first power level.

During the step 412 of receiving the first response set at the first power level, the system may be configured to selectively look for a single sponge type, corresponding to the first sponge type. Any response to the interrogation at the first power level that does not match the first sponge type may be automatically excluded from the first response set to reduce the volume of data to be processed.

The method 400 then includes the step 414 of comparing the first response set, in response to operating the RFID

reader at the first power level and different from the default power level, to the first package content information to determine an error status. Within the first response set are the unique identifications of all the tags present within the effective read range of the RFID reader at the first power level. Based on the response to step 404 of operating the RFID reader at the default level and receiving the first package content information, a comparison can be made to the first response set—the response from operating the RFID reader at the first power level.

In a situation where the package is complete—that is, no error is present—the first response set will properly contain the identification of all the sponges indicated by the first package content information. Where the first package content information is that of multiple sponges in a single package, this is an important verification that all of the expected articles are actually present so as to minimize errors or confusion for the HCP in managing the use of surgical articles during the surgical procedure and avoiding the undesirable retention of surgical articles within the patient following the surgical procedure. In this case, the complete package of surgical articles may be counted-in to the surgical procedure at step 416 and the articles may be placed in the appropriate staging area to be at hand for the HCP in the surgical procedure. The above steps, beginning with step 404 operating the RFID reader at the default power, may be repeated along branch 417 until the desired inventory of surgical articles has been counted-in and made available for the surgical procedure. As the RFID executes the steps described, different types of sponges may be encountered, having different package quantities and different associated power levels. The different power levels associated with the different package types maintains a preferred read range of between about 12 inches to about 36 inches between the RFID reader and the package of surgical sponge, regardless of sponge type.

Comparing the first response set with the first package content information may indicate that the package is not a complete package. Upon this determination at step 418, the HCP may be alerted to the error. This step may be performed in a variety of ways. For example, a visual alert may be displayed to the HCP on a display in communication with the RFID reader. The visual alert may display specific information about the error, such as identifying the type of sponge presented, the number and identity of responding tags, the number expected within the package, and the discrepancy between the two. In the alternative, or in addition, the HCP may be alerted to an error determination with other visual alerts such as illuminated or flashing lights on a display or on the RFID reader. The HCP may be alerted to an error with an audible alarm, or a tactile response, for example within the RFID reader. The tactile response may include a vibration pulse or pattern of pulses.

Upon being alerted to the error condition, the HCP may remedy the error, if possible, or may discard the incomplete package of sponges and move on to other packages provided in the inventory, proceeding along branch 419, and repeating the steps of method 400 beginning with operating the RFID scanner at a default power level and continuing until the desired inventory of surgical articles have been counted-in and made available for the surgical procedure.

Once the desired inventory of surgical articles has been counted-in, the HCP may proceed with the surgical procedure as step 420. Upon completion of the surgical procedure, the surgical articles are removed from the patient at step 422. Following removal from the patient, the surgical articles are counted-out, for example, by again reading the surgical

articles with the RFID reader at step **424**. In the alternative, counting-out the surgical article may include optically scanning a label provided on the surgical article, or manually entering information so as to designate the surgical article as counted-out.

During the count-out step **424**, the RFID reader may operate at a default power level. Alternatively, the RFID reader may operate at a power level corresponding to a power level parameter of a sponge type counted-in to the procedure and not yet counted-out. Where multiple sponge types are counted-in, with the sponge types having different associated power level parameters, the RFID reader may operate by performing sequential interrogation operations while cycling operations at different power levels associated with the different sponge types. The RFID reader may receive response sets and register only those responses from sponges of the type corresponding to the power level of the particular interrogation cycle, while excluding any response of other types of sponges not associated with the power level of the particular interrogation cycle.

The method **400** also includes the step **426** of displaying the status of the surgical article inventory. Although illustrated at the conclusion of the method shown in FIG. **4**, it is contemplated that this step may be performed persistently throughout the method, indicating the types of sponges responding to the RFID reader interrogation steps **406**, **412**, and maintaining a current count of counted-in and counted-out surgical articles as the surgical procedure proceeds. For example, displaying the status of the article inventory may include displaying a specific count of counted-in and counted-out surgical articles for each type of surgical article present. This display of the inventory status provides direct and immediate accounting of the surgical articles present for the surgical procedure to minimize the burden on HCPs in tracking and counting the use of surgical articles and ensuring that no surgical articles are retained in the patient following the surgical procedure.

A second method **500** of managing an inventory of surgical articles used during a surgical procedure is illustrated in FIG. **5**. The surgical articles may be surgical sponges **10**, as described above. Implementing the described method **500** assists HCPs in ensuring the proper removal of surgical articles following the surgical procedure. It should be appreciated that any feature/step of any method and system described herein may be used with the other methods and systems described throughout.

The method **500** includes a first step **502** of providing an inventory of surgical articles, such as surgical sponges. The inventory may be stored in a container, such as the mobile cabinet **112** shown in FIG. **2**. The inventory includes the packages of surgical articles. In a first example, the inventory includes at least a first package containing at least a first surgical sponge of a first sponge type. The first surgical sponge includes a first RFID tag storing a first unique identifier associated with the sponge, first package content information, and a first power level parameter associated with the first sponge type. The first package content information corresponds to the complete content of the first package. The use of designations of “first,” or “second” refer only to separate iterations of the count-in method steps and are not intended to be limiting or to require that “first” is different from “second” except where specifically denoted.

As described above, the package may include more than a single article, such as quantities of 2, 3, 5, 10, 20 or more within a single package. The unique identifier may be a single memory data field of an identification scheme stored on the RFID tag or may combine entries of multiple data

fields to constitute a single unique identifier. The package content information includes such information necessary to identify the unique package and the content of the package, such as quantity. In one example, the package content information relates to the unique package ID **126** of the identification scheme **120**, and may include sponge type ID **124**, to retrieve the complete package quantity, and the sponge number **128** identifying which position in the package a particular sponge occupies among the complete quantity.

The method **500** includes steps **504** of operating an RFID reader and **506** of receiving tag information in response to operating the RFID reader. To initiate this step, an HCP may provide an input to the RFID reader either directly or through some other connected piece of hardware. This step may include the HCP specifically presenting a package of RFID-tagged surgical articles to the RFID reader, or vice versa, positioning them so that the RFID reader is within an effective read range of the RFID reader. The preferred read range may be between 12 inches and 36 inches. The response to step **504** may include one or more tag data. For example, in an environment where multiple RFID tags are present, the RFID reader may employ anti-collision features or read, collect, and process multiple tag’s data in one read operation. For example, such anti-collision features are described in the industry standard ISO/IEC 15693-3:2009—Anticollision and Transmission Protocol. The RFID reader is in communication with or incorporates a computer processing device to execute the operations of the method. Information may be retained in a database stored on a memory of the RFID reader, of another computer processing device, or may be distributed among multiple computer processing devices. The description of any processing or computing step may be performed by the RFID reader, or another device which is in communication with the RFID reader.

Among the response data received, a first tag’s data is used for continuing the steps of the method **500**, the first tag’s data includes a first unique identifier and information sufficient to identify a sponge type. The information identifying the sponge type may include or may be used to retrieve an associated RSSI count-in threshold for the particular sponge type. The data upon which to continue the method **500** from this step **506** may be the first complete data received in the response time. Alternatively, the response of step **506** may prioritize the use of some types of sponges over other types of sponges or may use other criteria to designate or select a particular sponge to proceed with the steps of the method **500** in order.

Based on the first RFID tag data, the method **500** includes the steps **508** of determining the RSSI for the first RFID tag response, and **510** of comparing the determined RSSI with the tag information, including the RSSI threshold associated with the sponge type. The RFID reader may determine the RSSI for the first RFID tag response or it may communicate the information related to the first RFID tag response to another computing device, such as a system computer, for processing the first RFID tag response and determining the RSSI. The RSSI is determined as a measure of the power of the response signal relative to the power of the interrogation signal prompting the response.

If the determined RSSI for a particular tag is at or above the RSSI threshold associated with the sponge type, the associated sponge is counted-in to the surgical procedure for use therewith at step **512**. It is contemplated that tag responses which do not meet or exceed the associated RSSI threshold for the associated surgical article type do not

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signify an error about which the HCP must be alerted. Rather, a low RSSI may simply signify a tag response as environmental noise for example, from surgical articles stored nearby, but not intended for use in the surgical procedure. The steps of operating the reader **504**, receiving tag information **506**, determining **508** and comparing **510** the RSSI values may be continued and repeated until the desired inventory of surgical articles have been checked into the surgical procedure, as shown along branch **513**.

The method **500** includes the step **520** of displaying the status of the article inventory. Although illustrated at the conclusion of the method shown in FIG. **5**, it is contemplated that this step may be performed persistently throughout the method, indicating the types of sponges responding to the RFID reader interrogation steps **506**, and maintaining a current count of counted-in and counted-out surgical articles as the surgical procedure proceeds. For example, displaying the status of the article inventory may include displaying a specific count of counted-in and counted-out surgical articles for each type of surgical article present. This display of the inventory status provides direct and immediate accounting of the surgical articles present for the surgical procedure to minimize the burden on HCPs in tracking and counting the use of surgical articles and ensuring that no surgical articles are retained in the patient following the surgical procedure.

If a particular package of surgical articles is presented by an HCP for counting-in but is not acknowledged by the system, such as by updating the displaying step to add the package quantity and type as counted-in, the HCP may attempt to adjust the positioning of the package relative to the RFID reader by moving it closer to the RFID reader or centering the package in front of the reader. The HCP may attempt to count-in the package by rotating the package to adjust its orientation relative to the RFID reader, or combinations of moving and rotating the package relative to the RFID reader. In some instances, the determined RSSI of a particular article may never achieve the threshold RSSI associated with the article type. The HCP may discard the article as defective in this case. Failure to achieve a sufficiently strong responsive signal at a count-in phase may indicate that the article will fail to provide a responsive signal during a count-out phase, potentially leading to confusion in the HCP attempting to manage and account for the article inventory at the conclusion of the surgical procedure.

Once the desired inventory of surgical articles has been counted-in, the HCP may proceed with the surgical procedure as step **514**. Upon completion of the surgical procedure, the surgical articles are removed from the patient at step **516**. Following removal from the patient, the surgical articles are counted-out, for example, by again reading the surgical articles with the RFID reader at step **518**. In the alternative, counting-out the surgical article may include optically scanning a label provided on the surgical article, or manually entering information so as to designate the surgical article as counted-out.

During the count-out step **518**, the RFID reader may operate at a default power level and count-out sponges when a response to the interrogation signal is received and the sponges has been previously counted-in to the procedure. Alternatively, the RFID reader may operate by varying the power level for successive interrogation cycles according to the power level parameters associated with the sponge types counted-in to the procedure. In a further alternative, the RFID reader may combine the technique of variable power levels described above in step **424**, with an evaluation of the RSSI for a particular sponge to ensure that the proper sponge

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is being counted-out. In order to achieve the requisite RSSI during the count-out process, the sponge may be presented within a range of the RFID reader so that sponges remaining in the surgical field are not inadvertently counted-out.

Consistent with the above description, the method **500** includes displaying the status of the article inventory **520**, including, for example, providing an identification of counted-in and counted-out articles throughout the surgical procedure.

A further method **600** of managing an inventory of surgical sponges used during a surgical procedure is illustrated in FIG. **6**. Similar to the above methods **400**, **500**, the surgical articles may be surgical sponges **10**, as described above and the method may serve to assist HCPs in ensuring the proper removal of surgical sponges following the surgical procedure. Again, as in the above methods **400**, **500**, the method **600** includes a first step **602** of providing an inventory of surgical articles, such as surgical sponges. The inventory may be stored in a container, such as the mobile cabinet **112** shown in FIG. **2**. The inventory includes the packages of surgical articles. In a first example, the inventory includes at least a first package containing at least a first surgical sponge of a first sponge type. The first surgical sponge includes a first RFID tag storing a first unique identifier associated with the sponge, first package content information, and a first power level parameter associated with the first sponge type. The first package content information corresponds to a complete content of the first package. The use of designations of “first,” or “second” refer only to separate iterations of the count-in method steps and are not intended to be limiting or to require that “first” is different from “second” except where specifically denoted.

As described above, the package may include more than a single article, such as quantities of 2, 3, 5, 10, 20 or more within a single package. The unique identifier may be a single memory data field of an identification scheme stored on the RFID tag or may combine entries of multiple data fields to constitute a single unique identifier. The package content information includes such information necessary to identify the unique package and the content of the package, such as quantity. In one example, the package content information relates to the unique package ID **126** of the identification scheme **120**, and may include sponge type ID **124**, to retrieve the complete package quantity, and the sponge number **128** identifying which position in the package a particular sponge occupies among the complete quantity.

The method **600** includes steps **604** of operating an RFID reader and **606** of receiving tag information in response to operating the RFID reader **604**. The step **604** of operating the RFID reader includes operating the RFID reader at an initial power level for a first period of time. During this step **604**, the RFID reader collects a first response set during the first limited period of time. Based on the initial power level, the first response set is evaluated to determine whether a complete first package is present in the response set—that is, based on the collected tag responses, and the package content information of the tag responses, whether every article of a complete package is present in the response set as having responded to the RFID reader operating at the initial power level for the first period of time. Upon determining a complete package is present in the response set, the method **600** optionally includes a step of evaluating whether the complete package is of a type having an associated power level that matches the initial power level of the RFID reader in step **604**.

Upon determining that the complete package is present, and the complete package is of a type having an associated power level matching the initial power level, the articles within the complete package are counted-in to the surgical procedure at step 610. It may occur that a complete package is found but that the articles are not of a type having an associated power level that matches the initial power level and, in that case, the articles are not counted-in to the surgical procedure.

Once the articles are counted-in after the initial operation of the RFID reader at an initial power level for the first period of time, the RFID reader may be reconfigured, at step 612, to operate at an incremented power level, different from the initial power level. The method may begin with the RFID reader at a low power level and increment to a higher power level, or alternatively may begin with the RFID at a higher power level and increment to a lower power level. At higher power level, it may be more likely that background tag responses from nearby stored articles may be received at the RFID reader. At lower power levels, fewer tag responses may be received from densely packed surgical articles as the tags in close proximity to each other cause interference or attenuation of the RFID reader's interrogator signal. Therefore, it is beneficial to cycle through the range of power levels within the capability of the RFID reader to ensure that the proper set of RFID tagged articles are counted into the surgical procedure.

The steps of operating the RFID reader at incrementing power levels, receiving response sets, and counting-in packages when they are determined complete and are of a type having an associated power level matching the power level of the cycled operation may be continued, along branch 613, until the desired RFID tagged article inventory is counted into the procedure. Once the desired inventory of surgical articles has been counted-in to the surgical procedure, the HCP may proceed with the surgical procedure as step 614. Upon completion of the surgical procedure, the surgical articles are removed from the patient at step 616. Following removal from the patient, the surgical articles are counted-out, for example, by again reading the surgical articles with the RFID reader, at step 618. In the count-out step 618 the RFID reader may operate at a default power level. In an alternative, the count-out step 618 may be similar to the count-out step 424, or step 518, both described above. In an alternative, counting-out the surgical article may include optically scanning a label provided on the surgical article, or manually entering information so as to designate the surgical article as counted-out. Consistent with the above description, the method 600 includes displaying the status of the article inventory, including, for example, providing an identification of counted-in and counted-out articles throughout the surgical procedure.

In one execution example, an inventory of sponges is provided, such as an inventory 112, at a step 402. An RFID reader, such as RFID reader 108, is provided and is toggled to operate in a count-in mode by providing an input at touchscreen 104 or the RFID reader 108. The RFID reader 108 is configured to initially operate at a default power level value of 15 dBm, which is stored in one of the system computer 101 or the RFID reader 108. The RFID reader 108 performs an interrogation cycle, such as at step 404, and receives the first response set of interrogation responses from a portion of the inventory presented to the RFID reader for counting-in. The system 100, either in the system computer 101 or the RFID reader 108, evaluates the first response set in order to identify at least 30% of sponges within a single package, such as at step 406. The RFID

reader 108 determines two 18"×18" lap sponges are present in the first response set having the same unique package ID 126.

The RFID reader 108 reconfigures to operate at 14 dBm, such as at step 408, which is the power level parameter associated with the 18"×18" lap sponge type. The power level parameter is retrieved from a look-up table or database stored in the system computer 101 or the RFID reader 108. The RFID reader 108 performs an interrogation cycle at 14 dBm, such as at step 410. The RFID reader 108 receives the second response set, such as at step 412. The second response set includes response data from five 18"×18" lap sponges having the same Unique Pack ID 126, which represents a complete package. Optionally, the system may exclude any data in the second response set that does not correspond to the 18"×18" lap sponge type. The system 100 determines the complete package, such as at step 414, and counts-in the five 18"×18" lap sponges for use in the surgical operation, such as at step 416. The RFID reader 108 reconfigures to operate at the default power level and continues with the remainder of the inventory 112 until all necessary articles have been counted-in, such as at step 417. The RFID reader 108 follows the same sequence of detecting at least three out of ten 2"×2" gauze sponges in a package at the default power level, reconfiguring to operate at 25 dBm, and detecting ten out of ten sponges in a package at the 25 dBm power level to count-in a package of ten 2"×2" gauze sponges. Once the remainder of the inventory 112 has been counted-in, the surgery is performed with the counted-in articles, such as at step 420.

After the surgical operation has been completed, the counted-in articles are counted-out so that no articles are unintentionally retained in the patient following the procedure, such as at step 424. The RFID reader 108 is toggled to operate in the count-out mode by providing an input at touchscreen 104 or the RFID reader 108. The RFID reader 108 performs successive interrogation cycles at 14 dBm and 25 dBm in 300 ms intervals while looking for the counted-in 18"×18" lap sponges and the 2"×2" gauze sponges, respectively. The successive interrogations continue until all of one type of sponge is counted-out, after which successive interrogation cycles will occur only at the power level associated with the counted-in sponge type. Optionally, the system 100 may evaluate the RSSI associated with each sponge identified in the response set to ensure that a minimum response strength is present before the sponge is counted out.

Several descriptions have been discussed in the foregoing disclosure. However, the discussions herein are not intended to be exhaustive or limit any particular form. The terminology which has been used is intended to be in the nature of words of description rather than of limitation. Many modifications and variations are possible in light of the above teachings and the disclosure may be practiced otherwise than as specifically described.

What is claimed is:

1. A system for managing a supply of surgical sponges used during a surgical procedure to ensure proper removal of the surgical sponges following the surgical procedure, the supply comprising a first package containing a first surgical sponge of a first sponge type, wherein the first surgical sponge comprises a first RFID tag, the first RFID tag storing a first unique identifier associated with the first surgical sponge, first package content information, and a first power level parameter associated with the first sponge type, and wherein the first package content information corresponds to a complete content of the first package, the system comprising:

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an RFID reader configurable to operate at one of a plurality of power levels in response to receiving a power level parameter in response to an RFID read operation; and

a database configured to store data representing a status of the supply of surgical sponges identifying a counted-in quantity and a counted-out quantity,

wherein the RFID reader is configured to:

- operate at a default power level;
- receive the first unique identifier, the first power level parameter, and the first package content information;
- reconfigure to operate at a first power level, different from the default power level, corresponding to the received first power level parameter;
- operate at the first power level;
- receive a first response set at the first power level;
- identify the first surgical sponge as counted-in in a database record for the surgical procedure when the first unique identifier is present in the first response set; and
- compare the first response set to the first package content information to determine an error status.

2. The system of claim 1, comprising a display device configured to display an accounting of the supply of surgical sponges identifying the counted-in quantity and the counted-out quantity.

3. The system of claim 1, wherein the supply of surgical sponges comprises a second package containing a second surgical sponge and a third surgical sponge, the second and third surgical sponges being of a second sponge type, wherein the second sponge comprises a second RFID tag, the second RFID tag storing a second unique identifier associated with the second surgical sponge, second package content information, and a second power level parameter associated with the second sponge type, wherein the third sponge comprises a third RFID tag, the third RFID tag storing a third unique identifier associated with the third surgical sponge, the second package content information, and the second power level parameter associated with the second sponge type, wherein the second package content information corresponds to a complete content of the second package, and wherein the RFID reader is configured to:

- operate at the default power level;
- receive the second unique identifier, the second power level parameter, and the second package content information;
- reconfigure to operate at a second power level, different from the first power level, corresponding to the received second power level parameter;
- operate at the second power level;
- receive a second response set at the second power level;
- identify the second and the third surgical sponges as counted-in in the database record for the surgical procedure when the second and the third unique identifiers are present in the second response set; and
- compare the second response set to the second package content information to determine an error status.

4. The system of claim 3, wherein the first power level parameter and the second power level parameter are selected such that the first package and the second package each have a preferred read distance within a same read-in range of the RFID reader.

5. The system of claim 4, wherein the read-in range is between about 12 inches and about 36 inches.

6. The system of claim 1, wherein the RFID reader is configured to trigger an alert when the error status is determined.

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7. The system of claim 6, wherein the alert comprises any one of an audible alarm, a displayed warning, a tactile response, or a combination thereof.

8. The system of claim 1, wherein the error status is determined when the first response set does not match the first package content information.

9. The system of claim 1, wherein the first package contains a plurality of surgical sponges, each surgical sponge including an RFID tag storing a unique identifier associated with the surgical sponge, the first power level parameter, and the first package content information, the first package content information on each of the RFID tags including information to identify each other surgical sponge in the first package.

10. The system of claim 9, wherein no error status is determined when the first response set identifies each of the sponges indicated by the first package content information.

11. The system of claim 1, comprising the supply of surgical sponges.

12. The system of claim 1, wherein the RFID reader is configured to:

- responsive to identifying the first surgical sponge as counted-in:
  - reconfigure to operate at the default power level;
  - read the first RFID tag; and
  - identify the first surgical sponge as counted-out in the database record for the surgical procedure based on the reading of the first RFID tag; and
- display the status of the supply of surgical sponges identifying the counted-in quantity and the counted-out quantity based on the database record.

13. A method for managing surgical sponges used during a surgical procedure to ensure proper removal of the surgical sponges following the surgical procedure, the method comprising:

- providing a supply of surgical sponges, the supply comprising a first package containing a first surgical sponge of a first sponge type, wherein the first surgical sponge comprises a first RFID tag, the first RFID tag storing a first unique identifier associated with the first surgical sponge, first package content information, and a first power level parameter associated with the first sponge type, and wherein the first package content information corresponds to a complete content of the first package;
- operating an RFID reader at a default power level;
- receiving at the RFID reader the first unique identifier, the first power level parameter, and the first package content information;
- reconfiguring the RFID reader to operate at a first power level, different from the default power level, corresponding to the received first power level parameter;
- operating the RFID reader at the first power level;
- receiving a first response set at the first power level, the first unique identifier being present in the first response set;
- identifying the first surgical sponge as counted-in in a database record for the surgical procedure responsive to the first unique identifier being present in the first response set; and
- comparing the first response set to the first package content information to determine an error status.

14. The method of claim 13, wherein the supply of surgical sponges comprises a second package containing a second surgical sponge and a third surgical sponge, the second and third surgical sponges being of a second sponge type, wherein the second sponge comprises a second RFID tag, the second RFID tag storing a second unique identifier

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associated with the second surgical sponge, second package content information, and a second power level parameter associated with the second sponge type, wherein the third sponge comprises a third RFID tag, the third RFID tag storing a third unique identifier associated with the third surgical sponge, the second package content information, and the second power level parameter associated with the second sponge type, and wherein the second package content information corresponds to a complete content of the second package, the method comprising:

- operating the RFID reader at the default power level;
- receiving at the RFID reader the second unique identifier, the second power level parameter, and the second package content information;
- reconfiguring the RFID reader to operate at a second power level, different from the first power level, corresponding to the received second power level parameter;
- operating the RFID reader at the second power level;
- receiving a second response set at the second power level;
- identifying the second and the third surgical sponges as counted-in in the database record for the surgical procedure responsive to the second and the third unique identifiers being present in the second response set; and
- comparing the second response set to the second package content information to determine an error status.

15. The method of claim 14, wherein receiving the first response set and the second response set comprises, respectively, positioning the first package and the second package at a first preferred distance and a second preferred distance from the RFID reader, wherein the first power level param-

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eter and the second power level parameter are selected such that the first preferred distance and the second preferred distance are within a same read-in range of the RFID reader.

- 16. The method of claim 13, comprising:
  - positioning the RFID reader adjacent a sterile field in which the surgical procedure is performed; and
  - removing the first surgical sponge from the first package after identifying the first surgical sponge as counted-in.

17. The method of claim 13, wherein the first package contains a plurality of surgical sponges, each surgical sponge including an RFID tag storing a unique identifier associated with the surgical sponge, the first power level parameter, and the first package content information, the first package content information on each of the RFID tags including information to identify each other surgical sponge in the first package, the method comprising determining no error status based on the first response set identifying each of the sponges indicated by the first package content information.

- 18. The method of claim 13, comprising:
  - responsive to identifying the first surgical sponge as counted-in:
    - operating the RFID reader at the default power level;
    - reading the first RFID tag; and
    - identifying the first surgical sponge as counted-out in the database record for the surgical procedure based on the reading of the first RFID tag; and
  - displaying a status of the supply of surgical sponges identifying a counted-in status and a counted-out status based on the database record.

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